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CONFIDENTIAL – ATTORNEYS' EYES ONLY MATERIAL – SUBJECT TO CONFIDENTIALITY ORDER

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, and NOVARTIS AG, Plaintiffs, v. WOCKHARDT USA LLC and WOCKHARDT LIMITED and SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Civil Action No. 2:12-cv-03967-SDW-MCA [Consolidated with Civil Action Nos. 2:12-cv-04393, 2:13-cv-01028, 2:13-cv-02379, and 2:13-04669] FILED UNDER SEAL
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACCORD HEALTHCARE INC.; ACTAVIS LLC; APOTEX, INC.; APOTEX, CORP.; GLAND PHARMA LTD.; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES LTD.; EMCURE PHARMACEUTICALS USA, INC.; EMCURE PHARMACEUTICALS, LTD; FRESENIUS KABI USA, LLC; HIKMA FARMACEUTICA S.A.; HOSPIRA, INC.; PHARMACEUTICS INTERNATIONAL INC.; SAGENT PHARMACEUTICALS, INC.; ACS DOBFAR INFO S.A.; STRIDES, INC.; AGILA SPECIALTIES PRIVATE LTD.; SUN PHARMA GLOBAL FZE; CARACO PHARMACEUTICAL LABORATORIES, LTD.; SUN PHARMACEUTICAL INDUSTRIES LTD.; USV NORTH AMERICA, INC.; WOCKHARDT USA LLC; and WOCKHARDT LTD., Defendants.	

NOVARTIS'S RESPONSE TO CERTAIN DEFENDANTS' REQUESTS TO SUPPLEMENT THEIR MOTIONS TO DISMISS WITH AN FDA LETTER

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

The letter from the Food and Drug Administration (FDA) that certain defendants now seek to submit on the pending motions to dismiss is irrelevant. The Court should disregard defendants' submissions.

The pending motions concern Novartis's suit against generic drug makers that are seeking to sell a generic version of Novartis's "Reclast" brand drug. Novartis invented and patented methods of using Reclast's active ingredient zoledronic acid to treat osteoporosis. Doctors prescribe Reclast almost exclusively for that condition—99.7% of Reclast prescriptions are for osteoporosis. As a result, almost every use of Reclast would infringe Novartis's rights under U.S. Patent No. 8,052,987 (the "'987 patent").

But certain generics maintain they can evade the '987 patent and sell generic Reclast simply by using a drug label that avoids mentioning osteoporosis. The generics' labels provide indications solely for treating "Paget's disease," a condition rarely treated with Reclast—only 0.3% of Reclast prescriptions are for Paget's, or approximately 1,000 doses per year nationwide. Because Paget's is not covered by the '987 patent, the generics contend that a label containing directions only for that condition provides a free pass to evade Novartis's patent rights.

The patent laws cannot be so easily circumvented, as shown in Novartis's opposition to the generics' motions to dismiss. (See Dkt. No. 79, Novartis's May 24, 2013 Omnibus Opposition To Certain Defs.' Mot. To Dismiss ("Novartis Br.").) Whatever their labels say, the generics' clear intent is to sell generic Reclast to treat osteoporosis—indeed, discovery so far in this case shows that the generics project selling Reclast in volumes that are multiple orders of magnitude greater than would be sold to supply Paget's patients alone. The generics' intent to thereby violate Novartis's patent rights renders the generics liable for infringement under 35 U.S.C. §§ 271 (b), (c) and (e).

The FDA letter the generics now seek to introduce has nothing to do with these issues. The letter is a response to a Novartis Citizen Petition that asked FDA to review whether the generics' labels provided sufficient safety information for treating Paget's. In osteoporosis clinical trials, Novartis collected safety information applicable to all Reclast users, including Paget's patients. Deleting this osteoporosis-related data from the label could be unsafe for Paget's patients. Novartis accordingly recommended that FDA deny the generics' request to sell under a Paget's-only label without the additional safety information.

While FDA agreed with aspects of Novartis's Petition, FDA nonetheless found that deleting osteoporosis information would not render the drug "less safe or effective" for treating Paget's. FDA thus approved the generics' labels. But in doing so, FDA never examined whether the generics would violate Novartis's patent rights. FDA's role with respect to patents is ministerial. It stays out of patent disputes as a matter of policy, leaving such disputes to the courts. FDA also did not address whether the generics' true intent is to sell generic Reclast to treat osteoporosis, contrary to what their labels say. The FDA letter accordingly has no bearing on the pending motions to dismiss.

Nevertheless, the generics now argue that the Court should give the FDA letter "deference" under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)—a new legal theory not in their motions to dismiss. The generics are wrong. The FDA letter is irrelevant, and their effort to inject a new Chevron theory into the pending motions is also procedurally improper and substantively flawed. The Court should reject the generics' effort to inject the FDA letter into the pending motions to dismiss.

ARGUMENT

Two generic groups have filed separate submissions that attach the FDA letter. Apotex, Inc. and Apotex Corp. (together, "Apotex") request that the Court take "judicial notice" of the

letter. (Dkt. No. 177-1 ("Apotex Br.").) Pharmaceutics International, Inc. ("Pii") and others submit the letter as putative "supplemental authority." (Dkt. No. 175 ("Pii Br.").) FDA's letter is neither relevant nor authoritative on the issue of patent infringement, and the Court should disregard both submissions.

I. The FDA Letter Is Irrelevant To The Pending Motions To Dismiss

"[J]udicial notice is inappropriate where the facts to be noticed are irrelevant[.]" *Meador v. Pleasant Valley State Prison*, 312 F. App'x 954, 956 (9th Cir. 2009); *see also Whiting v. AARP*, 637 F.3d 355, 364 (D.C. Cir. 2011) ("Although the district court may take judicial notice in ruling on a motion to dismiss . . . the matters to be noticed must be relevant[.]"); *cf. In re: Congoleum Corp.*, 426 F.3d 675, 679 n.2 (3d Cir. 2005) (taking judicial notice only "insofar as . . . relevant"). Such is the case here, where the FDA letter is not relevant to any issue presented in the motions to dismiss. Likewise, the FDA letter is not "supplemental authority" for any issue that matters to the pending motions.

In that regard, the Federal Circuit has made clear that "FDA is not the arbiter of patent infringement issues." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061 (Fed. Cir. 2010); *see also aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002) (stating that FDA does not resolve patent disputes because "FDA has no expertise in making patent law judgments"). FDA agrees, acknowledging that it "lack[s] expertise in patent matters." Applications for FDA Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30–Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003). As FDA has explained, "reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are outside both [FDA's] expertise and [FDA's]

authority." *Id.*[1] The FDA letter accordingly does not purport to address any aspect of the present patent dispute, which alone is reason to reject defendants' submission of it here.

The letter instead addresses a single, narrow issue: whether the generics' Paget's-only labels are safe for Paget's patients. Novartis's Petition explained to FDA that, with a Paget's-only label, "physicians will not be informed of all precautions and warnings that need to be clinically considered when prescribing zoledronic acid to Paget's disease patients." (*See* accompanying September 23, 2013 Affidavit of Robert W. Trenchard ("Tren. Aff."), Ex. 1 (Novartis's Citizen Petition) at 1.) As a result, generic Reclast would be "less safe than Reclast for the treatment of Paget's disease, because physicians and other health-care providers would not have access to safety information necessary to the product's safe use in the approximately 1,000 patients being treated for Paget's disease." (*Id.* at 2.)

These safety issues arose because branded "Reclast labeling contains extensive data and information resulting from clinical trials evaluating its use in its four approved osteoporosis populations." (*Id.*) Novartis believes that this information "is essential to the safe and effective use of Reclast in *all* patients," including "physicians and other health-care professionals . . . treating Paget's disease patients[.]" (*Id.* (emphasis added).) Accordingly, the generics' strategy of "carving out . . . osteoporosis information from Reclast labeling would result in the omission of . . . information directly relevant to the product's safe use in treating Paget's disease[.]" (*Id.* at

[1] *See also* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,349 (Oct. 3, 1994) ("As stated elsewhere in this preamble, FDA lacks expertise in patent law."); *Pharmaceutical Marketplace Barriers: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (2003) (statement of Daniel E. Troy, Chief Counsel, U.S. Food & Drug Admin.) ("FDA lacks the authority, the resources, and the capability to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug."), *available at* http://www.fda.gov/NewsEvents/Testimony/ucm161034.htm.

4.) Novartis's Petition walks through specific safety issues presented by the omission of osteoporosis-related data from the generics' labels. (*Id*. at 4-6.)

In response to the Petition, FDA focused on the question presented by Novartis: whether a Paget's-only label is safe for Paget's patients. FDA "agree[d] that a significant amount of information would need to be carved out" to excise information about osteoporosis. (Tren. Aff. Ex. 2 (FDA Letter Responding to Novartis's Citizen Petition ("FDA Ltr.")) at 8.) But after analyzing the various safety concerns, FDA concluded that the "safety-related information related to the method of using [Reclast] for osteoporosis indications may be omitted from product labeling . . . without rendering the generic product less safe or effective than Reclast for the treatment of Paget's disease." (*Id*.)

None of these findings are relevant to the pending motions to dismiss. As reflected in the briefing of those motions, Novartis asserts three claims in this action, none of which have anything to do with the safety of the generics' label for Paget's patients:

First, the generics are liable for inducing infringement under 35 U.S.C. § 271(b). The crux of this claim is whether defendants specifically intend their customers to infringe Novartis's patent rights, and know that customers' acts constitute infringement. (Novartis Br. at 9.) The primary facts relevant to this claim concern the economics of selling generic Reclast. The generics *must* intend to sell generic Reclast to treat osteoporosis—any other plan would be irrational, as it would not even cover the cost of obtaining FDA approval for the generic drug. (*Id*. at 3-7.)

Further proof of the generics' intent is their expected sales. The available information shows that the generics expect to sell in volumes that are possible only if the generics are targeting generic Reclast for the treatment of osteoporosis. According to data gathered in

discovery prior to the motions to dismiss, [redacted] Through on-going discovery, [redacted] The generics thus have no intention of limiting their sales to the treatment of Paget's disease, and instead intend massive sales for the treatment of osteoporosis in violation of Novartis's patent rights.

The subject of the FDA letter—the safety of the generics' labels for Paget's patients—has nothing to do with these issues. What matters is the generics' intent to sell massive amounts of generic Reclast to osteoporosis patients in flagrant violation of Novartis's patent rights, and their creation of stockpiles to facilitate such sales.[2] The FDA letter does not address these issues at all, and is consequently irrelevant to Novartis's inducement claim.

More specifically, the FDA letter does not address whether the generics in fact intend to sell generic Reclast to treat osteoporosis. FDA expressly refused even to consider whether such sales "might" occur, much less whether the generics intend to pursue them. (FDA Ltr. at 12.) FDA could not have considered this question in any event. Novartis did not supply FDA with the generics' manufacturing and projected sales data. Nor, apparently, did the generics disclose this information to FDA. The FDA letter accordingly sheds no light on whether the generics intend to sell generic Reclast to treat osteoporosis in violation of Novartis's patent rights, and is thus irrelevant to Novartis's inducement claim.

[2] Reclast has a three-year shelf life, so the creation of substantial stockpiles proves that the generics intend to sell to far more than the 1,000 Paget's patients annually who each take only one dose of Reclast before being cured. (Novartis Br. at 6.)

Second, the generics are liable for contributory infringement under 35 U.S.C. § 271(c). On this claim, the central issue on the motions to dismiss is whether Paget's sales constitute a "substantial non-infringing use" for generic Reclast. (Novartis Br. at 17-19.) They do not. Sales for Paget's account for only 0.3% of Reclast's prescriptions, falling far short of "substantial."

The FDA letter says *nothing* about whether Paget's constitutes a "substantial non-infringing use" under the patent laws. To be sure, the generics contend that FDA's approval of Reclast to treat Paget's makes sales to treat that condition "substantial" as a matter of law. (*See* C.A. 13-01028, Dkt. No. 207, Apotex's Brief in Support of Its Motion to Dismiss at 22-25; C.A. 13-01028, Dkt. No. 209, Certain Defendants' Brief in Support of Their Joint Motion to Dismiss at 17-20). But the fact that FDA has approved Reclast for Paget's is undisputed, and the FDA letter adds nothing to the point. As shown in Novartis's opposition brief, FDA's approval of Reclast to treat Paget's does not transform sales for that condition into a "substantial non-infringing use." (Novartis Br. at 18-19.)

Third, the generics are liable for direct infringement under 35 U.S.C. § 271(e), which makes the filing of an infringing Abbreviated New Drug Application (ANDA) an act of direct infringement. (*Id.* at 20.) This claim depends on the generics' filing of misleading or improper submissions with FDA—called "Section viii carve-outs"—for approval to sell Reclast with a Paget's-only label. *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) (explaining that misleading Section viii carve-outs may merit a claim under 271(e).)

Novartis shows in opposition to the motions to dismiss that the generics' FDA submissions were misleading and improper in seeking labels that fail to provide directions for the drug's intended use in treating osteoporosis. (Novartis Br. at 20-23.) As shown in the opposition, the Food, Drug and Cosmetic Act and FDA regulations require drug sellers to use

labels for *all* "purposes for which [the drug] is intended." (*Id.* at 21 (quoting 21 C.F.R. § 201.5).) By omitting instructions for the drug's *intended* use in treating osteoporosis, the generics have rendered their Section viii carve-outs "misleading" and "improper" under *AstraZeneca*.

Discovery since the motion to dismiss has only further confirmed the misleading and improper nature of the generics' submissions. The ANDAs produced so far each contain an express certification that the generic would abide by the labeling requirements of 21 C.F.R. § 201, which includes the requirement that a generic label address all intended users of a drug. (*See* Tren. Aff. Ex. 4 (sample ANDA certification from Pii).) Given the facts showing that generics intend to sell generic Reclast to treat osteoporosis, these certifications are further evidence that the generics' submissions to the FDA contain an outright misrepresentation.

The FDA letter has no bearing on these issues. The letter reflects no analysis of whether the generics have complied with FDA regulations requiring that drugs contain labels for all "intended" uses. The FDA made no inquiry into intent at all. To the contrary, as noted above, FDA refused even to consider whether the generics "might" sell generic Reclast to treat osteoporosis. FDA certainly did not examine whether the generics actually intend to pursue such sales.

Nonetheless, Apotex argues that the FDA letter shows that the generics' Paget's-only labels are not "misleading." (Apotex Br. at 6.) Apotex contends that FDA's approval of the generics' label "although fully aware of Novartis's allegation about the potential for off-label use" means that "FDA has essentially rejected Novartis's interpretation of the applicable FDA regulations and statutes." (*Id.*) This assertion badly mischaracterizes the nature of the FDA letter, and of Novartis's position.

FDA made no analysis whatsoever of the generics' intent in selling generic Reclast. FDA's analysis focuses on whether the generic labels are safe and effective for Paget's patients, and FDA declined to consider whether generic Reclast "might" be used to treat osteoporosis. FDA did not address whether the generics *intend* to pursue such sales, or whether such intent renders their ANDAs misleading under 21 C.F.R. § 201.5. There is no evidence that FDA even had the pertinent facts before it, such as the generics' projected sales and manufacturing data presently before this Court. The FDA letter is accordingly irrelevant.[3]

II. Defendants' Submissions Are Procedurally And Substantively Deficient

As pretext for submitting the FDA letter, both Apotex and Pii contend that it is pertinent under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984), which requires courts to give "deference" to agency determinations "as to the meaning or reach of a statute." This argument is procedurally improper and substantively wrong.

As a procedural matter, no defendant has previously argued *Chevron* deference in the underlying motions to dismiss. So the generics' reference to *Chevron* is a new argument. A motion for judicial notice or an application to submit supplemental authority are not proper venues for making new arguments. *See United States v. Thompson*, 560 F.3d 745, 751 (8th Cir. 2009) (submission of supplemental authority not proper place for raising new arguments); *Siddiqui v. Holder*, 670 F.3d 736, 749 n.6 (7th 2012) (same); *United States v. Nason*, 9 F.3d 155, 163 (1st Cir. 1993) (same); *Trans-Sterling, Inc. v. Bible*, 804 F.2d 525, 528 (9th Cir. 1986) (same). The generics' submissions should be rejected for this reason too.

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[3] Apotex argues also that Section III of the FDA letter—which criticizes the timing of Novartis's Petition—is further proof that the generics' labels are not "misleading." (Apotex Br. at 7-8.) But that section, too, fails to address whether the generics intend to sell generic Reclast to treat osteoporosis. It is accordingly irrelevant. In addition, FDA's criticism of the timing of Novartis's Citizen Petition was based on an incomplete understanding of the facts, as set out in Novartis's request that FDA withdraw that section of its letter. (Tren. Aff. Ex. 5 (Novartis's Request to Supplement the Record and for Reconsideration).)

As a substantive matter, *Chevron* has no application here. *Chevron* applies only to a "decision as to the meaning or reach of a statute." *Chevron*, 467 U.S. at 844. The FDA does not purport to offer any decision on the meaning or reach of a statute. It merely assesses whether the generics' Paget's-only label is safe for Paget's patients. Presumably, that is why both Apotex and Pii only cite *Chevron* with a "*Cf*" citation—*Chevron* has no direct application here.

CONCLUSION

For the foregoing reasons, Novartis respectfully requests that the Court reject defendants' submission of the FDA letter.

Dated: September 23, 2013

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing NOVARTIS'S RESPONSE TO CERTAIN DEFENDANTS' REQUESTS TO SUPPLEMENT THEIR MOTIONS TO DISMISS WITH AN FDA LETTER was caused to be servied September 23, 2013, via email and/or ECF system upon all counsel of record.

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